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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/265,710	03/09/99	BANDMAN	O	PF-0339-1DIV

HM12/0515

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EXAMINER	
ULM, J	
ART UNIT	**PAPER NUMBER**
1646	7

DATE MAILED: 05/15/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/265,710	Applicant(s) Bandman et al.
	Examiner John Ulm	Group Art Unit 1646

☒ Responsive to communication(s) filed on *May 5, 2000*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1, 2, 12-18, and 21-40* is/are pending in the application.

Of the above, claim(s) *13-18, 23-35, and 40* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1, 2, 12, 21, 22, and 36-39* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *2*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1) Claims 1, 2, 12 to 18 and 21 to 40 are pending in the instant application. Claims 21 to 40 have been added as requested by Applicant in Paper Number 6, filed 05 May of 2000.

2) Claims 13 to 18 and 30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

3) Newly submitted claims 23 to 29, 31 to 35 and 40 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claims 23 to 29, 31 to 35 and 40 are drawn to an isolated nucleic acid and two methods of using that nucleic acid. The nucleic acid of these claims is a compound which is structurally and functionally different from the isolated polypeptide of the elected invention. Distinctness is shown by the fact that each of the claimed compositions can be made and used without the other. The purified polypeptide of invention I can be isolated from a natural source and, therefore, does not require the isolated polynucleotide now claimed. Lack of unity is further shown by the fact that these two different compositions, as claims, do not have a common utility which is based upon a common structural feature disclosed as the basis for that common utility. Applicant is advised that a **properly** dependant claim can not conceivably be infringed without infringing any of the claims from which it depends. The newly presented polynucleotide claims can not properly depend from polypeptide claims since the polynucleotide claims can be infringed by a composition which does not infringe the polypeptide claims.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 23 to 35 and 40 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4) Claims 1, 2, 12, 21, 22 and 36 to 39 are rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a credible biological role for this protein or its significance.

It is clear from the instant specification that the receptor protein described therein is what is termed an "orphan receptor" in the art. This is a protein whose cDNA has been isolated because of its similarity to known proteins. There is little doubt that, after complete characterization, this protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess

anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", " [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", " [i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to a protein of as yet undetermined function or biological significance. Until some actual and specific significance can be attributed to the protein identified in the specification as "NIMPH", or the gene encoding it, the instant invention is incomplete. The protein encoded by a DNA of the instant invention is a compound believed to function as a receptor simply because its amino acid sequence appears to contain a transmembrane domain. There is no evidence of record that NIMPH is actually expressed at the surface of a cell, binds to a ligand or transduces a signal. The only protein identified in the specification as related to NIMPH also has no demonstrated function. In the absence of a knowledge of the natural ligands or biological significance of this protein, there is no immediately obvious patentable use for it. To employ a protein of the instant invention in the identification of substances which inhibit or induce its activity is clearly to use it as the object of further research which has been determined by the

courts to be a utility which, alone, does not support patentability. The mere fact that this protein is allegedly expressed in cancer cell types, amongst others, is not relevant since thousands of "housekeeping" genes are expressed in all viable nucleated cells. Since the instant specification discloses that NIMPH is not expressed exclusively in cancer cells then there is no evidence to support a conclusion that this protein is diagnostic for a particular cancer. Since the instant specification does not disclose a credible "real world" use for NIMPH then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5) Claims 1, 2, 12, 21, 22 and 36 to 39 are rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

6) Claims 1, 2, 12 and 36 to 39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims encompass subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The text in the third paragraph on page 5 of the instant specification indicates

that the instant claims are intended to encompass "substantially purified NIMPH obtained from any species, particularly mammalian, including bovine, ovine, porcine, murine, equine, and preferably human, from any source whether natural, synthetic, simi-synthetic, or recombinant ". The instant specification, however, only describes an isolated nucleic acid encoding a single human protein and the disclosure of the "substantially purified polypeptide" encoded thereby is purely prophetic. Further, because of the presence of the "comprising" and "biologically active fragment" language in claims 1 and 21 and the fact that a "biologically active fragment can consist of nothing more than a glutamate residue, claim 21 encompasses any and all purified polypeptides and clam 1 encompasses any purified human receptor protein. However, the only composition which is described in the instant specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed composition was an isolated DNA encoding a single protein having the amino acid sequence presented in SEQ ID NO:1 of the instant application. In the recent decision *The Regents of the University of California v. Eli Lilly and Company,* 43 USPQ2d 1398 (CAFC 1997), the court held that:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is

claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood , 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Whereas the instant specification provides a detailed description of an isolated DNA encoding a single human protein having very specific physical and structural properties, the instant specification does not provide a written description of any other isolated nucleic acid or protein and certainly not the very broad genus of protein encompassed by the term "comprising" " a naturally-occurring amino acid sequence having at least 90% sequence identity to the amino acid sequence of SEQ ID NO:1" or "comprising" "a fragment thereof".

7) Claims 38 and 39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the claimed invention. A receptor agonist is a compound which reversibly binds to a receptor protein and

induces an activity by that protein. An antagonist is a compound which reversibly binds to a receptor protein and inhibits an activity of that protein. Because the instant specification does not identify any activity which is associated with a NIMPH protein of the instant invention an artisan can not possibly practice an assay which identifies an agonist or antagonist of that alleged receptor protein because that artisan does not know of an activity to assay as a measurement of the activation of inhibition of NIMPH in response to a test compound.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8) Claims 36 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims recited the limitation "an effective amount" without identifying the effect to be achieved.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9) Claims 1, 12, 21, 36, 38 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by the Prywes et al. publication (EMBO J. 5(9):2179-2190, 1986, for example. Because claim 21 encompasses any substantially purified polypeptide "comprising" "a biologically-active fragment of the amino acid sequence of SEQ ID NO:1" and a biologically

active fragment can consist of nothing more than a single amino acid, these claims encompass any and all substantially purified human transmembrane proteins. Claim 21 actually encompasses any and all purified polypeptides. Figure 2 on page 2181 of Prywes et al. described a substantially purified protein encompassed by claims 1, 12, 21 and 36 and an agonist/antagonist assay which anticipates claims 38 and 39.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kuntz can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JOHN ULM
PRIMARY EXAMINER
GROUP 1800